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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/295,464 04/19/99 ONG

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HM22/1107

EXAMINER

SCHNIZER, R

ART UNIT

PAPER NUMBER

1632

DATE MAILED:

11/07/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/295,464

Applicant(s)

ONG ET AL.

Examiner

Richard Schnizer

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 9 and 12-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9, 12 and 15 is/are allowed.
- 6) ☒ Claim(s) 1-6, 13, 14 and 16-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

An amendment was received and entered as Paper No. 12 on 8/17/01.

Claims 1-6, 9 and 12-19 are pending and under consideration in this Office Action.

Rejections Withdrawn

The rejection of claims 1-8, 9, 12, and 15 under 35 USC 112, second paragraph are withdrawn in view of Applicants amendments and comments.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 13, 14, and 16-18 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of screening for integration of a DNA construct into a target gene having expression restricted to a specific eukaryotic tissue or specialized eukaryotic cell *in vitro* or in a mouse, wherein two DNA constructs encoding separate indicator components are integrated into a cell, which is not a non-mouse ES cell, and which is subsequently used to form a tissue or a specialized cell *in vitro* or to form a mouse, does not reasonably provide enablement for the use of ES cells from an organism other than a mouse. The specification does not enable any person skilled in the art to which it pertains, or with which

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it is most nearly connected, to use the invention commensurate in scope with these claims, for the reasons of record in Paper No. 10.

Claims 1-6 and 16-18 are directed to methods of screening for insertion of a DNA construct into a target gene having expression restricted to a specific eukaryotic tissue or specialized eukaryotic cell. Claims 13 and 14 are directed to cells which are intended to be used in the methods of claims 1-6 and 16-18, and are included in the rejection for that reason.

The methods of claims 1-6 and 16-18 require the production of tissue or specialized cells. This limitation, when read in light of the specification, or in light of claim 19, can be considered to encompass the production of non-mouse transgenic animals which comprise the nucleic acid constructs of the invention. The specification fails to enable this scope of the invention for the reasons given in Paper Nos. 6 and 10. Briefly, the PTO has established the position that, at the time of the invention, non-mouse ES cells could not be used in processes which require transfection and/or selection procedures, while still retaining pluripotency. In other words the specification has not taught how to make non-mouse transgenic animals comprising the DNA constructs of the invention, and the specification has not taught how to induce non-mouse ES cells to differentiate into any type of specialized cell or tissue after transfection and/or selection procedures.

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Response to Arguments

Applicant's arguments filed 8/17/01 have been fully considered but they are not persuasive.

As a preliminary matter, it is noted that Applicant's arguments with respect to whether or not the first construct needs to be integrated into the cell are considered to be persuasive, and this portion of the rejection is withdrawn. However, as noted above, the rejected claims continue to embrace the formation of non-mouse transgenic animals and the use of non-mouse ES cells which have been subjected to transfection and selection procedures. These embodiments are not enabled for the reasons of record. Applicant has not responded to this aspect of the rejection, other than to indicate a lack of understanding as to why claims 13 and 14 were included in the rejection. This issue was addressed above.

Conclusion

Claims 9, 12, and 15 are allowable. All claims are free of the art of record.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached at 703-305-6608. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Patsy Zimmerman whose telephone number is 703-308-8338.

Richard Schnizer, Ph.D.



JAMES KETTER
PRIMARY EXAMINER